Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 5-20-2016.

Submission # 2

As of May 9, 2016, this submission has not been accepted for oral presentation at the meeting.

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Thursday, April 28, 2016 9:44 AM
To: Gennrich, Jane - Medicaid
Subject: FW: Request and Review for Brilinta Medicaid Testimonial for Medicaid P&T May 20th Meeting
Attachments: Fulfillment for Interaction 01100219.pdf

I think this is public testimony.

Tami Eide, Pharm.D., BCPS
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208-364-1829
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From: Do Not Reply [mailto:medinfo-donotreply@astrazeneca.com]
Sent: Thursday, April 28, 2016 9:01 AM
To: Eide, Tamara J. - Medicaid
Subject: Request and Review for Brilinta Medicaid Testimonial for Medicaid P&T May 20th Meeting

Dear Dr. Tami Eide,

Thank you for your inquiry regarding BRILINTA® (ticagrelor) Tablets. Attached is the Brilinta Medicaid Testimonial for Medicaid P&T May 20th Meeting.

In order to view the attached file, you must have Adobe® Acrobat Reader installed on your computer. If you do not have this software installed, you can download it at no cost from http://www.adobe.com or contact AstraZeneca LP at 1-877-893-1510 in order to receive this information via an alternative delivery method.

If we may be of further assistance to you, please contact AstraZeneca at 1-877-893-1510.

Please do not respond to this e-mail. This is an automatically generated notice from a system mailbox, which is not monitored.

Thank you,

Sara Parambil, Pharm.D.

April 28, 2016

Tami Eide, Pharm.D.
3232 Elder Street
Boise, ID 83705

Dear Dr. Eide:

Thank you for your inquiry regarding BRILINTA® (ticagrelor) Tablets. The following information is being provided, as a professional courtesy, in response to your request:

BRILINTA Medicaid Testimonial Idaho May 2016

These materials may include information that is not found in the currently approved prescribing information for BRILINTA® (ticagrelor) Tablets. The enclosed information is intended to provide pertinent data in response to your request and should in no way be construed as a recommendation for the use of this product in any manner other than as approved by the Food and Drug Administration and as described in the prescribing information for BRILINTA® (ticagrelor) Tablets. Please consult the Warnings and Precautions section of the prescribing information for further details and other important safety information. Prescription drugs used in a manner other than their approved indication may not be eligible for reimbursement by any third-party payors, including Medicaid, Medicare, or similar federal or state programs. Prescribing information for BRILINTA® (ticagrelor) Tablets may be obtained from www.astrazeneca-us.com or by calling the Information Center at AstraZeneca at 1-800-236-9933.

Adverse Event Reporting

In order to monitor the safety of BRILINTA® (ticagrelor) Tablets, we encourage clinicians to report suspected adverse events to AstraZeneca at 1-800-236-9933.

Thank you for your interest in BRILINTA® (ticagrelor) Tablets. If we may be of further assistance to you, please contact AstraZeneca at 1-877-893-1510.

Sincerely,

Sara Parambil, Pharm.D.
Senior Medical Information Manager

INQ 01100219

Summary of new clinical data in the BRILINTA Medicaid Testimony:

Please refer to the following lines for new clinical data for BRILINTA

- **Lines 5-13** – The 2016 ACC/AHA Guideline Focused Update on Duration of Antiplatelet Therapy states that BRILINTA is preferred over clopidogrel for the management of ACS (NSTE-ACS and STEMI) in patients who have received a coronary stent. It also states that continuation of DAPT for longer than 12 months may be reasonable in patients with ACS (NSTE-ACS or STEMI) treated with coronary stent implantation who have tolerated DAPT without a bleeding complication and who are not at high bleeding risk.

- **Lines 20-30**– The PEGASUS trial evaluated BRILINTA 90 mg or 60 mg twice daily plus low dose aspirin, versus placebo plus aspirin, for the long-term reduction in thrombotic CV events in 21,162 patients with a history of MI (1-3 years prior to randomization) and 1 additional risk factor. BRILINTA 60 mg plus aspirin was superior to placebo plus aspirin alone in reducing the rate of thrombotic CV events in prior MI patients. BRILINTA was associated with higher rates of the primary safety endpoint, TIMI major bleeding, and dyspnea versus placebo. This was driven by all 3 components of the primary endpoint: CV Death, MI, and stroke.

This information is being provided, as a professional courtesy, in response to your request. These materials may include information that is not found in the currently approved prescribing information for BRILINTA. The enclosed information is intended to provide pertinent data in response to your request and should in no way be construed as a recommendation for the use of this product in any manner other than as approved by the Food and Drug Administration and as described in the prescribing information for BRILINTA. Prescribing information for FDA approved AstraZeneca products may be obtained from www.astrazeneca-us.com or by calling the Information Center at AstraZeneca at 1-800-236-9933. For further medical information requests, please contact AstraZeneca at 1-877-893-1510.

Sushma Patel, Pharm.D.
Regional Clinical Account Director
AstraZeneca LP, Wilmington, DE

BRILINTA® (ticagrelor) Medicaid Testimonial

- BRILINTA is indicated to reduce the rate of CV death, MI, and stroke in patients with ACS or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel. BRILINTA also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS.[1]
- The updated ACC/AHA guidelines on the duration of DAPT therapy state that BRILINTA is preferred over clopidogrel for the management of ACS (NSTE-ACS and STEMI) BRILINTA is also preferred over clopidogrel in NSTE-ACS patients treated with medical therapy alone (without revascularization or fibrinolytic therapy) (Class IIa LOE: B-R).[2]
- The updated ACC/AHA Guidelines state that continuation of DAPT (clopidogrel, prasugrel, or ticagrelor) for longer than 12 months may be reasonable in patients with ACS (NSTE-ACS or STEMI) treated with coronary stent implantation who have tolerated DAPT without a bleeding complication and who are not at high bleeding risk (e.g., prior bleeding on DAPT, coagulopathy, oral anticoagulant use), (Class IIb, LOE: A SR).[2]
- BRILINTA is included as a class I recommendation for the management of patients with ACS undergoing PCI for at least 12 months in the [ACCF/AHA/SCAI] guidelines for PCI,[3] the [AHA/ACC] guidelines for NSTE-ACS,[4] the [AHA/ACCF] guidelines for STEMI[5] and Secondary Prevention and Risk Reduction.[6] The [AHA/ACC] guidelines for NSTE-ACS[4] and [AHA/ACCF] Secondary Prevention and Risk Reduction Guidelines[6] also include a Class I recommendation for the use of BRILINTA in the management of ACS in patients not invasively managed.
- The PEGASUS trial evaluated BRILINTA 90 mg or 60 mg twice daily plus low dose aspirin, versus placebo plus aspirin, for the long-term reduction in thrombotic CV events in 21,162 patients with a history of MI (1-3 years prior to randomization) and 1 additional risk factor.[7]
- BRILINTA 60 mg plus low dose ASA was superior to placebo plus aspirin in reducing the rate of thrombotic CV events (composite of CV death, MI, or stroke) in prior MI patients with a relative risk reduction (RRR) of 16% and an absolute risk reduction (ARR) of 1.27% at 3 years. BRILINTA was associated with higher rates of the primary safety endpoint, [Thrombolysis In Myocardial Infarction] (TIMI) major bleeding and dyspnea versus placebo.[7]
- BRILINTA 60 mg plus aspirin was superior to placebo plus aspirin alone in reducing the rate of thrombotic CV events in prior MI patients. This was driven by all 3 components of the primary endpoint: CV Death, MI, and stroke.[7]
- The most commonly reported adverse reactions were bleeding and dyspnea.[1]
- AstraZeneca strongly believes in Patient Health First. In ACS patients who have just experienced a potentially life-threatening event, unrestricted access to BRILINTA will facilitate the ability of physicians to prescribe a medication that has greater efficacy and comparable PLATO major bleeding, with somewhat greater Non-CABG bleeding relative to the current standard of care, clopidogrel.[1]
- There are boxed warnings for BRILINTA related to an increased risk of bleeding and reduced effectiveness with maintenance doses of aspirin greater than 100 mg per day. Please refer to the BRILINTA Prescribing Information for complete product information, including full Boxed Warnings and Warnings and Precautions.[1]
- AstraZeneca requests that BRILINTA be added on the preferred drug list for the Idaho Medicaid Program.

Reference(s):

[1] BRILINTA Prescribing Information.
[2] Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease. *J Am Coll Cardiol.* 2016; doi:10.1016/j.jacc.2016.03.513. Available at: http://circ.ahajournals.org/content/early/2016/03/28/CIR.0000000000000404.full.pdf+html.
[3] Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol.* 2011;58(24):e44-122.
[4] Amsterdam EA, Wenger NK, Brindis RG, et al 2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2014;64(24):2645-2687.
[5] O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;61(4):485-510.
[6] Smith SC Jr, Benjamin EJ, Bonow RO, et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation. *Circulation.* 2011;124(22):2458-2473.
[7] Bonaca MP, Bhatt DL, Cohen M, et al, for the PEGASUS-TIMI 54 Steering Committee and Investigators. Long-term use of ticagrelor in patients with prior myocardial *N Engl J Med.* 2015; 372:1791-800.